

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 1 097 676 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
09.05.2001 Bulletin 2001/19

(51) Int Cl.7: A61B 18/00

(21) Application number: 99308759.2

(22) Date of filing: 04.11.1999

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

• Vantassel, Robert A.
Excelsior, Minnesota 55331 (US)
• Holmes, David R.
Rochester, Minnesota 55906 (US)

(71) Applicant: Transvascular, Inc.
Menlo Park, CA 94025 (US)

(74) Representative: MacGregor, Gordon
Eric Potter Clarkson,
Park View House,
58 The Ropewalk
Nottingham NG1 5DD (GB)

(72) Inventors:
• Schwartz, Robert S.
Rochester, Minnesota 55902 (US)

(54) Device for forming holes in tissue

(57) A surgical instrument (10) for creating holes of a predetermined diameter and depth in body tissue comprises a tubular catheter (12) having a compression spring (20) affixed at its distal end and attached to the distal end of that spring is a tissue ablating device (22) which may, for example, comprise an electrosurgical monopolar or bipolar electrode that is connected by conductors extending through the lumen (18) of the catheter to an electrosurgical generator at its proximal end.

When the instrument is brought in contact with target tissue with a force sufficient to compress the coils of the spring against one another and then ablating energy applied, tissue will be removed as the spring is allowed to expand out to its uncompressed length. The depth of the hole thus created is equal to the difference (d) between the lengths of the spring when compressed and uncompressed. If desired, a suitable drug can be delivered into the thus created hole via a lumen in the catheter.

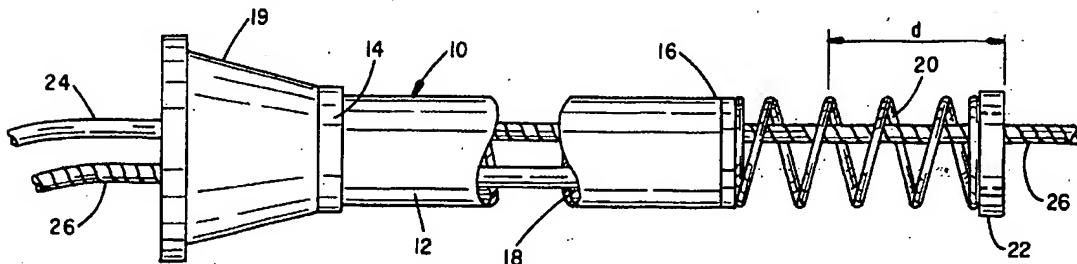


FIG. 1

EP 1 097 676 A1

Description**BACKGROUND OF THE INVENTION****I. Field of the Invention:**

[0001] This invention relates generally to surgical instruments, and more particularly to a device for creating holes of a predetermined depth into body tissue.

II. Discussion of the Prior Art:

[0002] In conducting various surgical procedures, it often becomes desirable to form a hole of a given diameter through tissue in such a way that the depth of penetration can also be accurately controlled. A procedure referred to as transmyocardial revascularization (TMR) may be applied endocardially or epicardially in revascularizing ischemic tissue. Here, small holes are drilled in the myocardium to allow blood to reach areas of the heart normally served by arteries or arterioles but which may have become occluded due to coronary artery disease. Also, where an artery has become so obstructed that a guide wire commonly used in percutaneous transluminal coronary angioplasty procedures cannot be passed, a need exists for an instrument to bore through the stenotic lesion in a controlled fashion so that the affected artery is not perforated.

[0003] Instruments especially designed for carrying out atherectomy procedures in larger arteries generally involve a catheter supporting a rotatable cutting blade on a distal end thereof for cutting through stenotic lesions and with suction being applied to remove the debris created during the cutting procedure. Generally speaking, the depth of penetration is controlled strictly by the operator in advancing the catheter. The instrument itself has no built-in structure for controlling the depth of penetration.

[0004] A need therefore exists for a surgical instrument that can safely be used in either open surgical procedures or in laparoscopic or intravascular procedures to create a hole of a predetermined diameter and desired depth dimension in multiple incremental uniform steps in target tissue structures.

SUMMARY OF THE INVENTION

[0005] The present invention provides a surgical instrument for forming holes of a predetermined diameter and depth dimension in selected tissue. In accordance with a preferred embodiment, it comprises an elongated catheter or tubular sheath having a proximal end, a distal end and a lumen extending between these two ends. A compression spring or spring-loaded cutting tip of a predetermined length dimension, when uncompressed is affixed to and extends from the distal end of the catheter. A tissue ablating device is carried by the compression spring and is adapted to be pressed against the

selected tissue in which a hole is to be bored with sufficient force to compress the spring. When the tissue ablating device is energized, a portion of the selected tissue abutting the ablating device is removed, allowing

5 the spring to expand to its uncompressed length dimension. Thus, the depth of penetration is equal to the difference between the compressed and uncompressed length of the coil spring.

[0006] The tissue ablating device may comprise an 10 electrode on the spring tip adapted to be energized by RF energy or, alternatively, an optical fiber adapted to be energized by a source of laser energy. A third alternative would be to use an ultrasonic transducer on the spring tip capable of crushing and emulsifying animal tissue which then can be aspirated through the lumen of the catheter.

DESCRIPTION OF THE DRAWINGS

20 [0007] The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

25 Figure 1 is a side elevational view of the tissue drilling instrument of the present invention; Figure 2 is a right end view of the instrument of Figure 1;

30 Figure 3 is a partial side view of an alternatively shaped electrode for use with the instrument of Figure 1; Figure 4 is a partial side view of the distal end portion of an alternative embodiment in which the penetration depth of the instrument can be varied; and

35 Figure 5 is a partial side view of the distal end portion of a further alternative embodiment having a telescoping ablation member.

40 DESCRIPTION OF THE PREFERRED EMBODIMENT

[0008] Referring to Figure 1, there is indicated generally by numeral 10 a surgical instrument for forming holes in tissue structures where the holes are of a pre-determined diameter and depth dimension. It comprises

45 an elongated tubular member 12 having a proximal end 14 and a distal end 16 and with a lumen 18 extending therebetween. Affixed to the proximal end of the tubular body member 12 is a molded plastic hub 19 which may take on a variety of configurations but in Figure 1 is shown as a simple female Luer connector.

[0009] Affixed to the distal end of the tubular body member 12 is a compression spring 20 of a pre-determined length dimension such that the difference, d , between its fully compressed condition and its uncompressed condition will control the depth of the hole to be formed in the tissue, all as will be described in greater detail below.

[0010] Affixed to the distal end of the compression spring 20 is a tissue ablating device 22. The tissue ablating device 22 may comprise an electrosurgical electrode (monopolar or bipolar) that is adapted to be coupled, via an insulated conductor, passing through the lumen 18 to a radio frequency electrosurgical generator of conventional design (not shown).

[0011] The tissue ablating device 22 may alternatively comprise a lens for focusing laser energy delivered through the tubular catheter body 12 by an optical fiber whose proximal end is coupled to a source of laser light.

[0012] The tissue ablating device 22 may also be an ultrasonic transducer that is connected by electrical conductors passing through the lumen 18 of the catheter for connection to a ultrasound power supply (not shown) coupled to the proximal end of the instrument 10.

[0013] The catheter 12 may be rigid when intended for use in an open surgical procedure or a laparoscopic procedure, but for intravascular applications, the catheter body 12 is preferably formed from a flexible plastic material, such as are commonly used in the manufacture of diagnostic coronary catheters that may be introduced, for example, into the femoral artery and advanced over a guide wire until the tissue ablating device is disposed adjacent target tissue to be penetrated. To accommodate passage over a guide wire, such as guide wire 26 in Figure 1, it is preferable that the tissue ablating device 22 be provided with an opening 28 therethrough, as shown in the distal end view of Figure 2. Also, the opening may permit drug delivery to the target site via the guidewire lumen.

[0014] Figure 3 illustrates an alternative shape configuration which may be advantageously used when being advanced against tissue that is at an angle to the longitudinal axis of the catheter. By providing a sharpened tip 30 on the tissue ablating device 22', any tendency for the tissue ablating device to slide along the tissue structure will be inhibited.

[0015] In using the hole forming instrument 10 of Figure 1, the operator will advance the catheter 12 until the tissue ablating device 22 on the distal end thereof is brought into engagement with the target tissue. The catheter will then continue to be advanced with sufficient force to compress the spring 20 so that its coils abut one another. Now, by energizing the tissue ablating device 22 while holding the catheter stationary, the tissue structure in which it is in contact will be ablated allowing the spring 20 to extend its full length, creating a hole in the tissue whose depth is the difference between the compressed length and uncompressed length of the spring 20. If it is desired to increase the depth of penetration into the tissue, after de-energizing the tissue ablating device 22, the catheter 12 can again be advanced in the distal direction to the point where the spring 20 is again fully compressed. At this point, a second energization of the tissue ablating device 22 will again result in the expansion of the spring 20 to its full length thereby effectively doubling the hole depth. Because each step is

of a precise, known length, the composite hole depth can be accurately determined.

[0016] In the embodiment of Figure 1, the extent of advancement of the tissue ablating device into the target tissue upon energization is determined by the particular spring 20 employed on the catheter. Figure 4, which shows only the distal end portion of the instrument of Figure 1, is designed to allow the surgeon to set the distance that the spring is allowed to expand. Here, the catheter body 12 has an end cap 32 having a clearance bore 34 formed through it and an annular pattern of ratchet teeth formed on its proximal facing side. A spring 20' is affixed to the end cap 32 and attached to the opposite end thereof is a tissue ablating device 22'. Completing the assembly is a threaded screw 36 that is affixed to the device 22' and that passes through the center of the helix comprising compression spring 20' and through the clearance bore 34 of the end cap 32 into a nut 38 having matching ratchet teeth on its distal facing surface. By rotating the device 22', the degree of extension of the spring and its attached tissue ablating device becomes adjustable. More particularly, with the teeth on the nut 38 mating with those on the end cap 32, rotation of screw 36 adjusts the span between the end cap and the ablating device 22'. With the device abutting the target tissue, a pushing force applied to the catheter 12' will disengage the ratchet teeth on the nut from those on the end cap and will compress the spring to the point where its coils abut one another. Now, when the energy is applied to the ablating device 22' and tissue is removed, the spring can only expand to the extent permitted by the screw 36.

[0017] Figure 5 is a cross-sectional and partial view of the distal end portion of the hole forming catheter comprising a further preferred embodiment. In this arrangement, the tissue ablating device 22' is slidably received within the lumen 18" of the catheter body 12" and a portion thereof projects beyond the distal end 16" of the catheter body. Formed internally of the lumen 18" is an annular stop 40 against which the proximal end of the spring member 20" abuts. The distal end of the spring 20" cooperates with the tissue ablating device 22', normally urging it in the distal direction. Depending on the nature of the tissue ablating device, energization therefore may be conveyed either over electrical conductors 24" that extend through the lumen 18" or via an optical fiber where laser energy is employed.

[0018] As with the above-described embodiments, when used, the catheter 10" is percutaneously inserted into the body and routed therethrough until the tissue ablating device 22" abuts the target tissue where a hole is to be created. The catheter is continued to be advanced until the spring 20" is fully compressed such that its coils abut one another. While holding the catheter stationary, the tissue ablating device 22" is appropriately energized with electrical or light energy to thereby ablate tissue against which it is placed. As the tissue disintegrates, the spring 20" is allowed to expand and advance

the tissue ablating device 22" until the spring is fully extended. If a hole of an increased depth is desired, the foregoing step may be repeated a number of times with each iteration resulting in a penetration distance equal to the difference between the compressed length and uncompressed length of the spring 20".

[0019] With either embodiment, it is possible to inject a drug into the newly created tissue perforation by coupling a syringe to the Luer fitting 19 and injecting the drug through the lumen 18 and out the central opening of the annular tissue ablating device 22.

[0020] This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

Claims

1. Apparatus for forming holes of a predetermined depth and diameter dimension in selected tissue comprising:

- (a) an elongated catheter having a proximal end, a distal end and a lumen extending therebetween;
- (b) a compression spring having first and second ends, the spring being of a predetermined length dimension when uncompressed with the first end being affixed proximate the distal end of the catheter and with the spring extending longitudinally therefrom; and
- (c) a tissue ablating device operatively coupled to the second end of said compression spring such that upon actuation, said spring expands linearly to provide longitudinal displacement of said tissue ablating device, and adapted to be pressed against said selected tissue with sufficient force to compress said spring with subsequent energization of the tissue ablating device ablating tissue distal to the tissue ablating device and allowing the spring to expand to its uncompressed length dimension.

2. The apparatus as in Claim 1 wherein the tissue ablating device comprises an electrosurgical electrode.

3. The apparatus as in Claim 2 and further including at least one electrical conductor passing through said lumen and conductively connected to the elec-

tosurgical electrode.

4. The apparatus as in claim 1 wherein the tissue ablating device comprises an optical fiber and a source of laser energy coupled to said optical fiber.

5. The apparatus as in Claim 4 wherein the optical fiber extends through said lumen.

10 6. The apparatus as in Claim 2 wherein the electrosurgical electrode is an annulus.

7. The apparatus as in Claim 2 wherein the electrosurgical electrode includes a sharp point.

15 8. The apparatus as in any one of Claims 2 and 4 wherein the compression spring and at least a portion of said tissue ablating device is contained within said lumen.

20 9. A method for forming holes of a predetermined length in selected tissue in a patient comprising the steps of:

- 25 (a) providing a catheter having a proximal end, a distal end and a lumen extending therebetween, said catheter having a compression spring of said predetermined incremental length when uncompressed disposed on said distal end of the catheter with the spring supporting a tissue ablating device thereon;
- (b) routing said catheter percutaneously to reach said selected tissue;
- (c) pressing the tissue ablating device against the selected tissue with a force sufficient to fully compress the spring;
- (d) energizing the tissue ablating device to ablate the selected tissue sufficient to allow the spring to expand to its predetermined incremental length; and
- (e) repeating steps (c) and (d) until a hole of a desired length in the tissue has resulted.

30 10. The method of claim 9 and further including the step of injecting a drug through the lumen and into the hole following step (e).

35 11. Apparatus for forming holes of a predetermined depth and diameter dimension in a selected tissue comprising:

- 40 (a) an elongated catheter having a proximal end, a distal end and a lumen extending therebetween;
- (b) a compression spring of a predetermined length dimension when uncompressed affixed proximate the distal end of the catheter; and
- (c) a tissue ablating device operatively coupled

to said compression spring, the tissue ablating device including an optical fiber extending through said lumen and a source of laser energy coupled to the optical fiber, the tissue ablating device adapted to be pressed against said selected tissue with sufficient force to compress said spring and with subsequent energization of the source of laser energy, ablating tissue distal to the compression spring and allowing the spring to extend to its uncompressed length dimension.

5

10

15

20

25

30

35

40

45

50

55

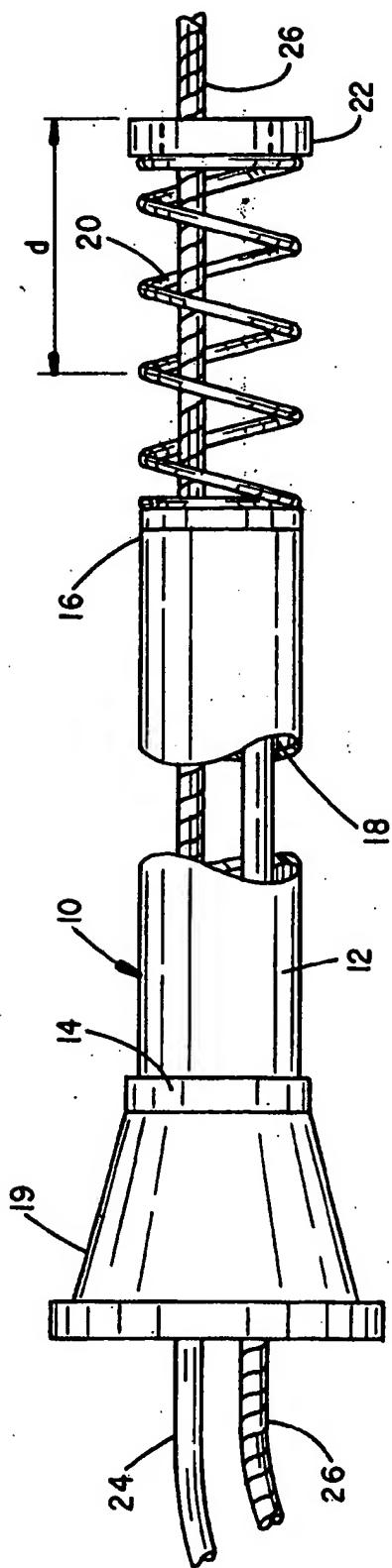


FIG. 1

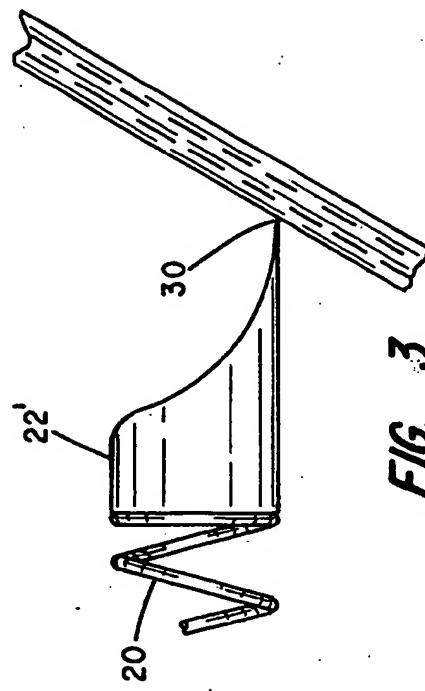


FIG. 3

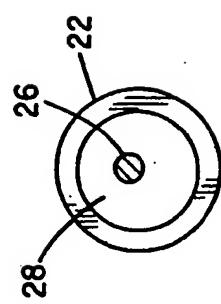


FIG. 2

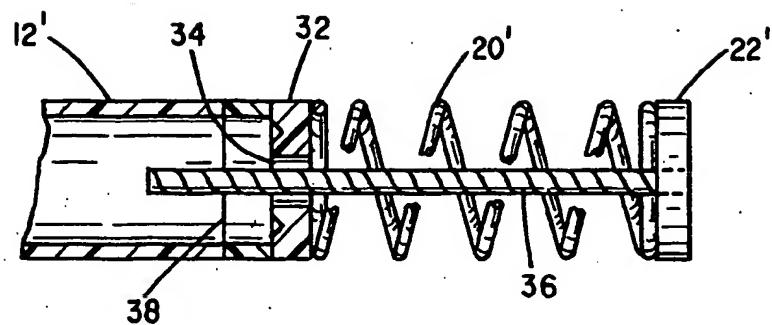


FIG. 4

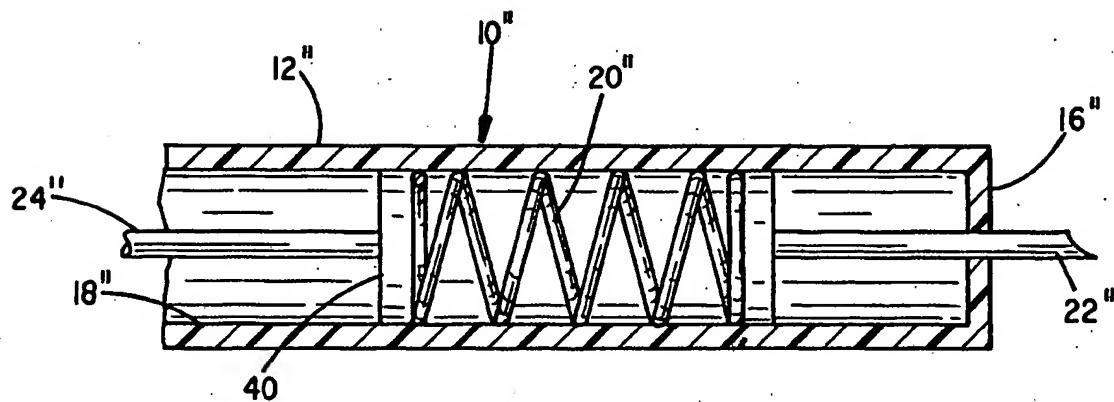


FIG. 5



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 99 30 8759
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)										
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim											
Y	EP 0 801 928 A (ECLIPSE SURGICAL TECH) 22 October 1997 (1997-10-22) * column 9, line 41 - line 49; figures 6,7 *	1-5,7,8, 11	A61B18/00										
Y	WO 98 27877 A (ADVANCED CORONARY INTERVENTION) 2 July 1998 (1998-07-02)	1-5,7,8, 11											
A	* page 4, line 22 - line 29; figures 1,3 * 6												
A	EP 0 868 923 A (ECLIPSE SURGICAL TECH) 7 October 1998 (1998-10-07) * column 14, line 20 - line 26; figures 9A,B *	1,11											
A	US 5 968 059 A (ELLIS LOUIS ET AL) 19 October 1999 (1999-10-19) * column 5, line 7 - line 8; figure 7 *	1,11											
A	EP 0 807 417 A (UNITED STATES SURGICAL CORP) 19 November 1997 (1997-11-19) * column 11, line 15 - line 25; figures 21-25 *	1,11											
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)										
			A61B										
INCOMPLETE SEARCH													
<p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims</p> <p>Claims searched completely: 1-8,11</p> <p>Claims searched incompletely</p> <p>Claims not searched: 9,10</p> <p>Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>													
Place of search THE HAGUE		Date of completion of the search 30 March 2000	Examiner Mayer, E										
<p>CATEGORY OF CITED DOCUMENTS</p> <table> <tr> <td>X : particularly relevant if taken alone</td> <td>T : theory or principle underlying the invention</td> </tr> <tr> <td>Y : particularly relevant if combined with another document of the same category</td> <td>E : earlier patent document, but published on, or after the filing date</td> </tr> <tr> <td>A : technological background</td> <td>D : document cited in the application</td> </tr> <tr> <td>O : non-written disclosure</td> <td>L : document cited for other reasons</td> </tr> <tr> <td>P : intermediate document</td> <td>& : member of the same patent family, corresponding document</td> </tr> </table>				X : particularly relevant if taken alone	T : theory or principle underlying the invention	Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date	A : technological background	D : document cited in the application	O : non-written disclosure	L : document cited for other reasons	P : intermediate document	& : member of the same patent family, corresponding document
X : particularly relevant if taken alone	T : theory or principle underlying the invention												
Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date												
A : technological background	D : document cited in the application												
O : non-written disclosure	L : document cited for other reasons												
P : intermediate document	& : member of the same patent family, corresponding document												

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 8759

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information

30-03-2000

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0801928	A	22-10-1997	US 5738680 A AU 1668697 A CA 2201538 A JP 10024046 A US 6019756 A	14-04-1998 09-10-1997 05-10-1997 27-01-1998 01-02-2000
WO 9827877	A	02-07-1998	AU 5905098 A	17-07-1998
EP 0868923	A	07-10-1998	US 5876373 A AU 5845398 A CA 2233898 A JP 10295822 A	02-03-1999 08-10-1998 04-10-1998 10-11-1998
US 5968059	A	19-10-1999	EP 0971757 A WO 9839038 A	19-01-2000 11-09-1998
EP 0807417	A	19-11-1997	US 5807383 A AU 2084297 A CA 2205163 A JP 10057389 A	15-09-1998 20-11-1997 13-11-1997 03-03-1998

EPO FORM P049

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82